AUG 2 7 2004

12 510(k) Summary K041997

Radionics XKnife RT 3 with Non Stereotactic Module 510(k) Summary

This summary of the 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. 807.92.

1.0 The submitter of this premarket notification is:

Kevin J. O'Connell
Senior Regulatory Associate
Radionics, a division of Tyco Healthcare Group LP
22 Terry Avenue
Burlington, MA 01803
Tel.: (781) 272-1233
Fax: (781) 272-2428

This summary was prepared on July 21, 2004.

2.0 The name of the device is the Radionics XKnife RT 3 with Non Stereotactic Module. The common name is Radiotherapy Treatment Planning System, and its classification name is Medical charged-particle radiation therapy system.

3.0 The above device is substantial equivalent to the Radionics XPlan 2.2 with the Body System was cleared via 510(k), K013661, on December 03, 2001; Radionics XKnife 4 Stereotactic RTP System was cleared via 510(k), K981055, on September 29, 1998; and ADAC Laboratories, Inc. Pinnacle3 Radiation Therapy Planning System, Version 6.6 was cleared via 510(k), K032724, on October 9, 2003. .

4.0 The device is a module of the XKnife RT system that allows radiotherapy treatment planning use non-stereotactic CT image sets. As in traditional radiation treatment planning, external markers on the patient (rather than a stereotactic frame) now provide a reference from which an isocenter may be specified.

5.0 XKnife RT 3 with Non-Stereotactic Module is a radiosurgery and radiotherapy treatment planning system intended for use in stereotactic and non-stereotactic, collimated beam, computer planned, LINAC based treatment.

6.0 Sufficient testing has been completed to insure that the module can import, localize and generate a treatment plan using a non-stereotactic CT scan.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2004

Mr. Kevin J. O'Connell
Senior Regulatory Associate
Radionics, a division of Tyco Healthcare LP
22 Terry Ave.
BURLINGTON MA 01803

Re: K041997
Trade/Device Name: Radionics XKnife RT3 with Non Stereotactic Module
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 23, 2004
Received: July 26, 2004

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

ODE Indications for Use Statement

510(k) Number (if known): K041997

Device Name: Radionics XKnife RT 3 with Non Stereotactic Module

Indications for Use:

XKnife RT 3 with Non-Stereotactic Module is a radiosurgery and radiotherapy treatment planning system intended for use in stereotactic and non-stereotactic, collimated beam, computer planned, LINAC based treatment.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR § 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041997